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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,553	05/29/2001	Karola Rittner	032751-050	4015

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,553	RITTNER ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 5/29/01 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-16 are pending examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 300.

II. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 6, classified in class 530, subclass 300.

III. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 7, classified in class 530, subclass 300.

IV. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 8, classified in class 530, subclass 300.

V. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 9, classified in class 530, subclass 300.

VI. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 10, classified in class 530, subclass 300.

VII. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 11, classified in class 530, subclass 300.

VIII. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 12, classified in class 530, subclass 300.

IX. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 13, classified in class 530, subclass 300.

X. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain,

which comprises the amino acid sequence of SEQ ID NO: 14, classified in class 530, subclass 300.

XI. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 15, classified in class 530, subclass 300.

XII. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 16, classified in class 530, subclass 300.

XIII. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 17, classified in class 530, subclass 300.

XIV. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 18, classified in class 530, subclass 300.

XV. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 19, classified in class 530, subclass 300.

XVI. Claims 1-14, drawn to a cationic peptide, which is capable of causing membrane disruption and which does not comprise an amino acid with an acidic side chain, which comprises the amino acid sequence of SEQ ID NO: 20, classified in class 530, subclass 300.

XVII. Claims 15 and 16, drawn to a method for curative treatment of mammals comprising administering an effective amount of the complex of claim 6 to a patient in need thereof, classified in class 424, subclass 1.69.

XVIII. Claims 15 and 16, drawn to a method for preventive treatment of mammals comprising administering an effective amount of the complex of claim 6 to a patient in need thereof, classified in class 424, subclass 1.69.

XIX. Claims 15 and 16, drawn to a method for vaccine treatment of mammals comprising administering an effective amount of the complex of claim 6 to a patient in need thereof, classified in class 424, subclass 1.69.

XX. Claim 16, drawn to an *in vitro* method for transferring an anionic substance of interest to a cell comprising the cationic peptide of claim 1, classified in class 424, subclass 1.69.

Note: If applicants elect group XVII, XVIII, XIX, or XX and add claims directed to a specific peptide, which comprises the amino acid sequence set forth in SEQ ID NOs: 2 and 6-20, applicants are required to elect a specific SEQ ID NO:.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the distinct amino acid sequences in inventions I-XVI are distinct and the specification does not disclosed them as capable of used together. The amino acid sequence in Inventions I-XVI has a different function or different effect. Furthermore, it has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the 1(one) sequence is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Invention I-XVI and Inventions XVII, XVIII, XIX, and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the complex in Invention I-XVI can be used in materially different processes as set forth in Groups XVII, XVIII, XIX, and XX. The methods in Groups XVII, XVIII, XIX, and XX can be practiced with any product in groups I-XVI. In addition, the method can be used to deliver an anionic substance (e.g., anti-sense, mRNA, protein) other than DNA.

Invention XVII and Inventions XVIII, XIX, and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to distinct therapeutic methods that have different mode of operation, function and effect and the specification does not disclose that the methods in groups XVII-XX are capable of use together. Each method requires a different patient that would not be required in the other methods. In addition, the *in vitro* method in Invention XX has a different mode of operation and different effect. The anionic substance required for each method is not disclosed as capable as use together with the other methods and the anionic substance for use in each method would display a different mode of operation, different function and different effect.

Claim 1 link(s) inventions I-XVI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claim 16 link(s) inventions XVII-XX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for any other Group and the search is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER